

Risk Assessment and Risk-Based Cleanup

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What is Risk Assessment?

A process used to:

- Organize information
- Analyze information

Provides estimates of harm from exposure to a agent.

We do risk assessments every day when selecting how to act or react!

An Every Day Risk Assessment!

Let's Buy a Lottery Ticket

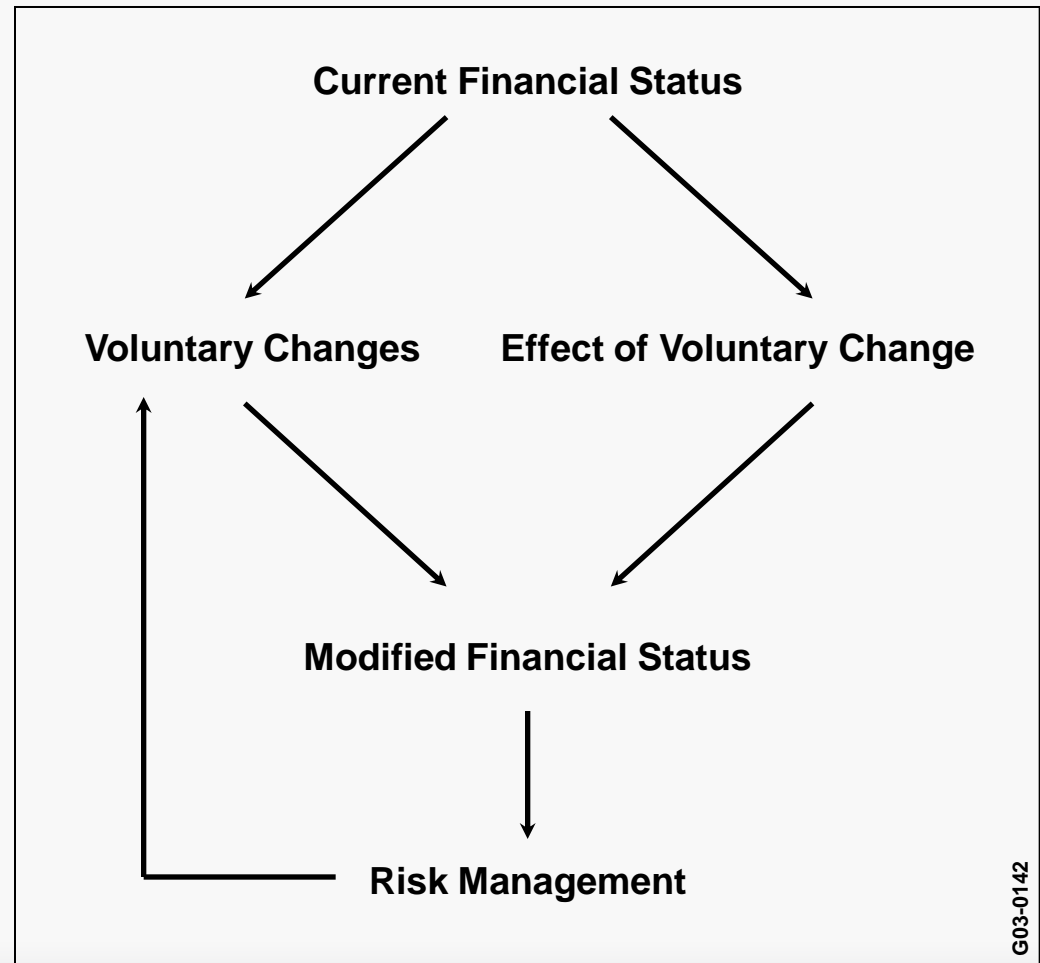
Expectation is to win!

How much to spend?

What is the chance of winning?

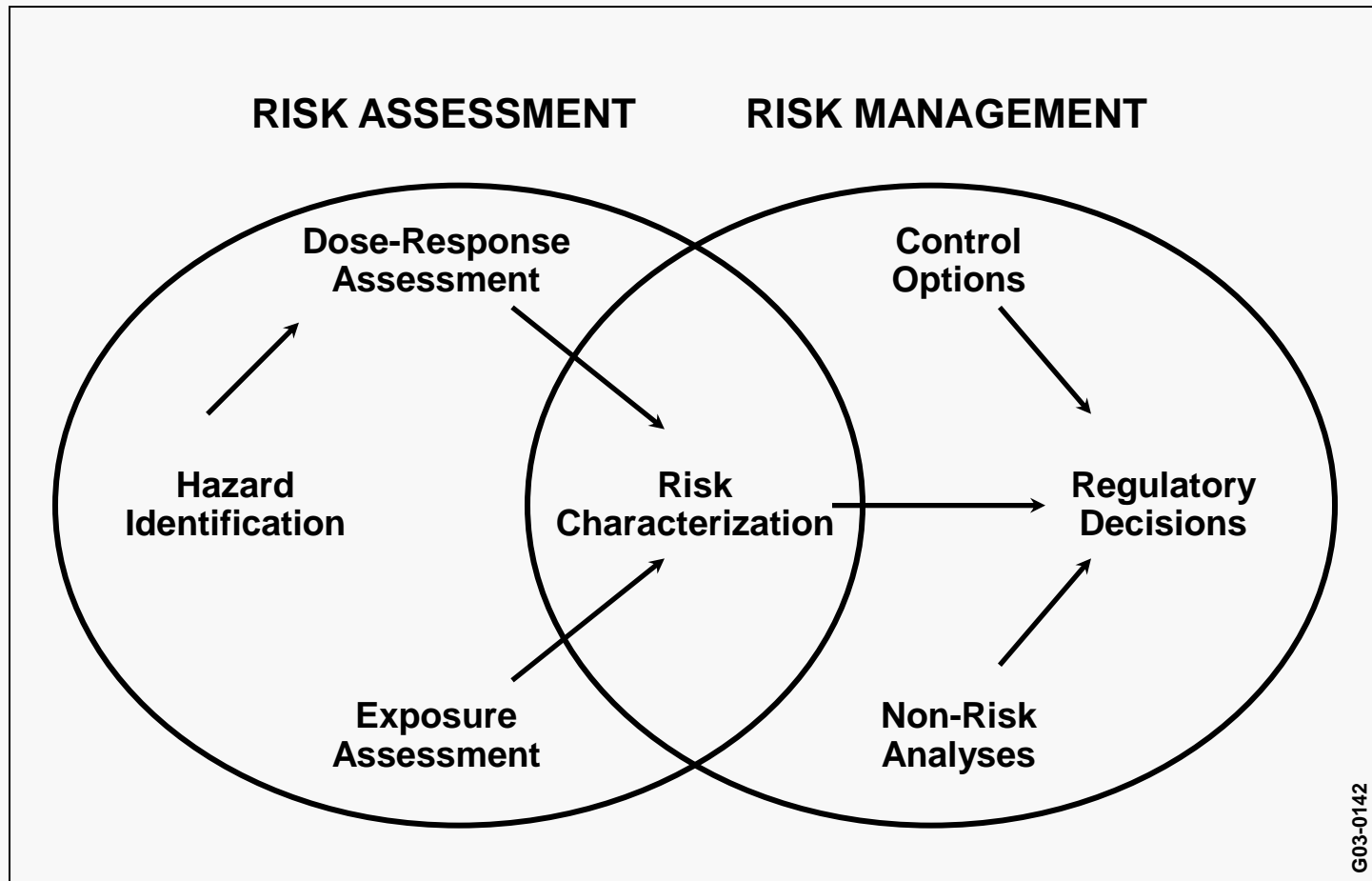
Can you increase your chances of winning?

**Once result is obtained, resulting risk is managed!
(Buy another ticket?)**



Can You Paradigm?

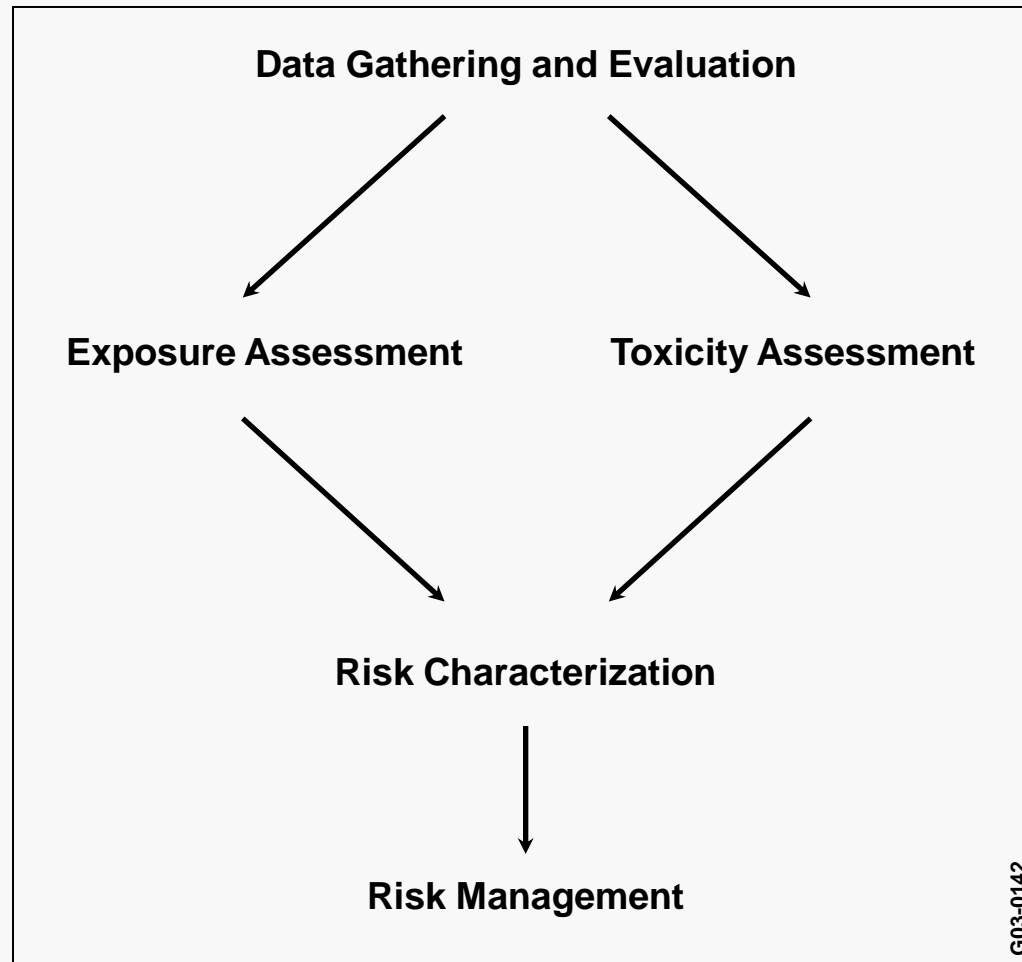
How is this similar to the everyday example?



National Academy of Sciences Risk Paradigm

EPA's Risk Assessment Paradigm

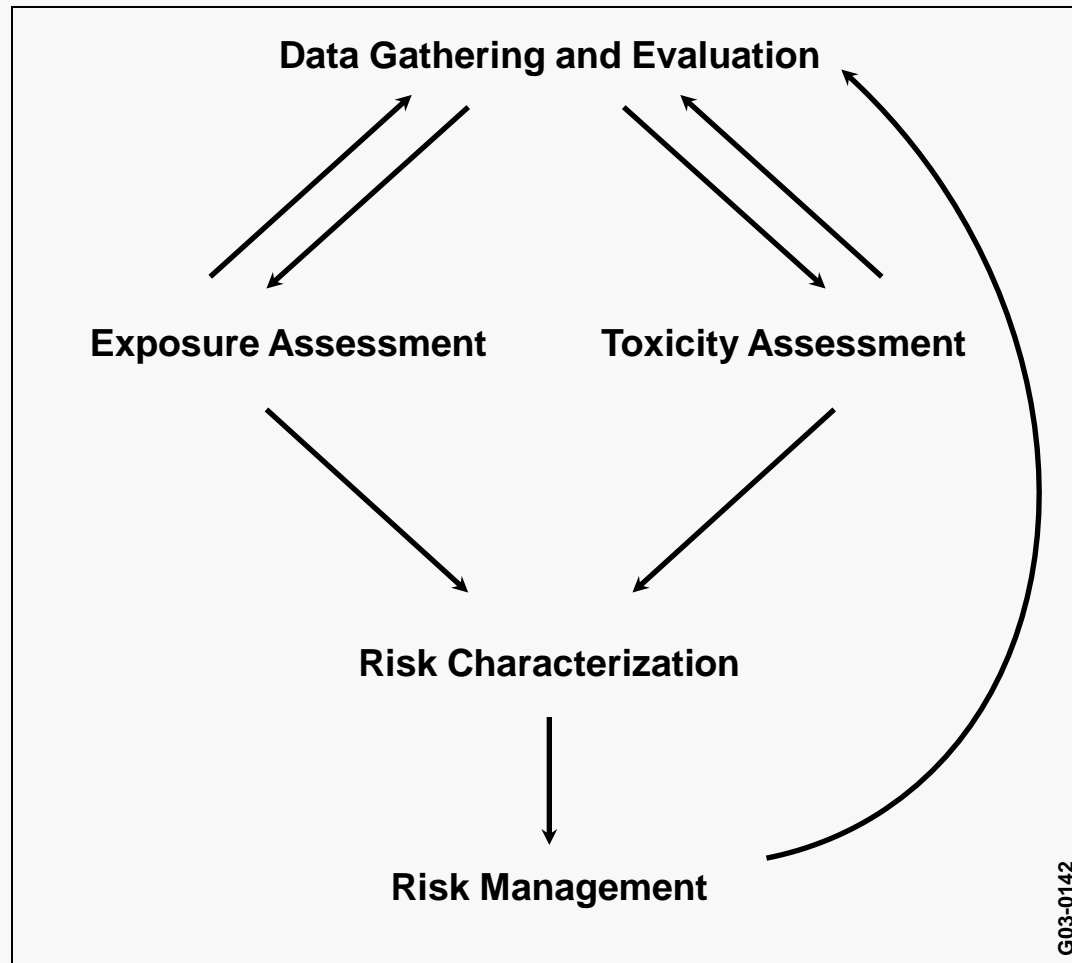
Let's Flip It and Simplify!



EPA Environmental Risk Paradigm (from "RAGS")

EPA's Risk Assessment Paradigm

Add Some Feedback Loops!



EPA Environmental Risk Paradigm (from "RAGS")

The Parts Defined!

Data Gathering and Evaluation:

Demonstrate the presence of a harmful agent

==> How much is there?

Exposure Assessment:

Calculate projected rate of contact by receptor

==> What is the dose or intake?

Toxicity Assessment:

Demonstrate relationship between level of exposure and injury

==> What harm does the agent cause?

Risk Characterization:

Calculate measure of expected effect by integration toxicity and exposure assessments

==> What is the risk?

The Parts Defined!

Risk Management

- ***Control Options:***

Actions that may be taken to reduce effects

==> Methods to reduce risk?

- ***Non-risk Inputs:***

Consideration of social and economic consequences

- ***Regulatory Decision:***

Response action decision

==> What is done!

Risk Management is where the "rubber meets the road!"

Some Additional Detail on Parts

Data Gathering and Evaluation – Analyze Contamination

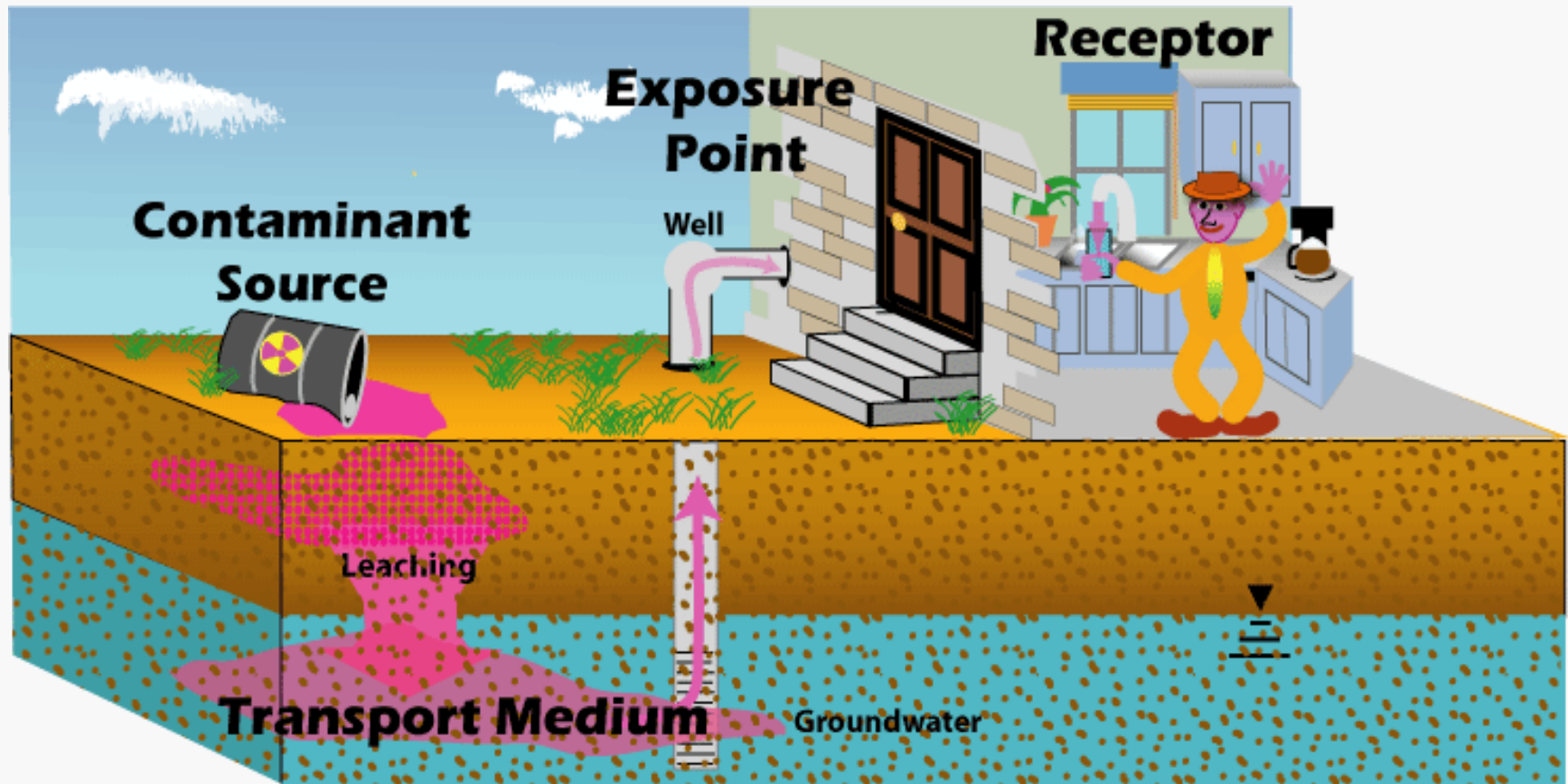
- Is sampling of sufficient quality and representative of site conditions?
- Is contamination present in samples? (Compare to background)
- Is contamination present at concentrations that could cause harm? (Above *de minimis* levels)
- End up with “Contaminants of Potential Concern” or “COPCs”

Exposure Assessment – Estimate Dose

- Develop conceptual site model
 - How could exposure occur?
 - Who may be exposed?
- Calculate dose or intake by integrating contaminant concentrations and rate of exposure

$$\text{Intake} = \text{Concentration} \times \left[\frac{\text{Contact Rate} \times \text{Exposure Frequency}}{\text{Body Weight}} \times \frac{1}{\text{Averaging Time}} \right]$$

An Example Conceptual Site Model



Some Additional Detail on Parts

Toxicity Assessment – Assess Potential Health Effects

- **Cancer effects:**

- Potential for cancer to occur in response to exposure to a contaminant.
- Toxicity value is called a slope factor.

- **Non-cancer effects:**

- Potential for injury to occur in response to exposure to a contaminant.
- Toxicity value is called a reference dose (RfD).

Some Additional Detail on Parts

Risk Characterization - Calculating cancer risk

- Integrate contaminant intake with slope factor.
- Results are in terms of probability

$$\text{Cancer Risk} = \text{Slope Factor} \times \text{Intake}$$

Risk Characterization - Calculating hazard

- Integrate contaminant intake with reference dose.
- Results reported as fractions or multiples of reference dose.

$$\text{Hazard} = \frac{\text{Intake}}{\text{Reference Dose}}$$

Interpretation of Risk Results

Benchmarks for Cancer Risk

- $<1 \times 10^{-6}$ (probability is less than 1 in 1 million)
Cancer risk is at *de minimis* levels; cleanup likely not needed.
- $>1 \times 10^{-4}$ (probability is greater than 1 in 10 thousand)
Cancer risk is at an elevated level; cleanup likely needed.
- $>1 \times 10^{-6}$ but $< 1 \times 10^{-4}$ (probability is greater than 1 in 1 million but less than 1 in 10,000)
Cancer risk is in “gray area;” evaluate options for cleanup.

10^{-6} to 10^{-4} is called, “EPA’s acceptable risk range for site-related exposures to carcinogens.”

Comparison of Cancer Risks

Cancer-causing Agent or Situation	Approximate Lifetime Risk of Cancer	Scientific Notation
Exposure to Sun (skin cancer)	1 in 3	3E-01
Cigarette smoking (pack a day or more)	8 in 100	8E-02
Natural radon in indoor air in home	1 in 100	1E-02
Outside radiation (radon and cosmic rays)	1 in 1,000	1E-03
Second-hand cigarette smoke	7 in 1,000	7E-03
Human-made chemicals in indoor air in home	2 in 10,000	2E-04
Outdoor air in industrialized area	1 in 10,000	1E-04
Human-made chemicals in drinking water*	1 in 100,000	1E-05
Human made chemicals in food	1 in 100,000 or less	$\leq 1E-05$
a) 2 oz. peanut butter per week from aflatoxin	8 in 100,000	8E-05
b) One meal per year of small lake trout from Lake Michigan	1 in 100, 000	1E-05
Chemical exposure at most uncontrolled hazardous-waste sites	1 in 10,000 to 1 in 1,000,000	1E-04 to 1E-06

From U.S. EPA Region 5 report *Environmental Risk: Your Guide to Analyzing and Reducing Risk* (EPA 905/9-91/017, October 1991).

Available at <http://www.epa.gov/reg5oopa/reisk/htm>.

Interpretation of Risk Results

Benchmarks for Hazard

- < 1 (hazard is below threshold level)
Hazard is at *de minimis* levels; cleanup likely not needed.
- > 1 (hazard is above threshold level)
Hazard is at an elevated level; evaluate options for cleanup.

Identifying the Problems

Contaminants of Concern (COCs)

- COPCs that have an unacceptable level of risk or hazard within a scenario that has an unacceptable level of risk or hazard are COCs.
- Cleanup goals are developed for COCs during risk management.

Cleanup Goals

- Specific to the cleanup action that is selected.
- Integrate exposure and concentration.

Putting It All Together – An Example

Site Description

- Spill of solvent (trichloroethene) occurred.
- Over time, trichloroethene migrated to groundwater.
- Trichloroethene detected in groundwater at the spill site and in neighboring wells.
- Trichloroethene detected in soils at spill areas.

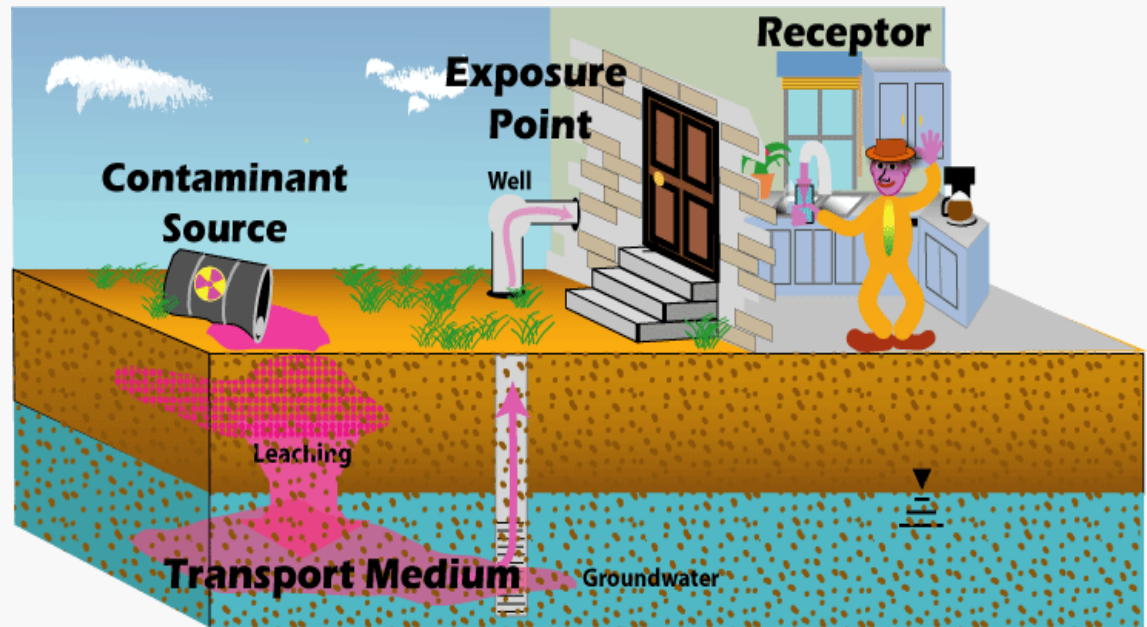
Sampling Shows (Data Gathering and Evaluation)

- Trichloroethene in groundwater (at well) averages 30 micrograms/liter.
- Trichloroethene in soil (at source) averages 200 milligrams/kilogram.

Putting It All Together – An Example

Receptor is adult that:

- Drinks from the well
- Contacts contaminated soil



Some “exposure parameters:”

- Water ingestion – 2 liters/day
- Incidental soil ingestion – 100 mg/day
- Days per year exposed – 350 days/year
- Years exposed – 30 years
- Body weight of adult – 70 kg (154 lbs)

Trichloroethene toxicity factors

- Slope Factor = $0.322 \text{ [mg/(kg X day)]}^{-1}$
- Reference Dose = $0.0003 \text{ mg/(kg X day)}$

(Source 2010 Paducah Risk Methods Document)

Putting It All Together – An Example

Use Equations for Intake, Cancer Risk, and Hazard Calculation

$$\text{Intake} = \text{Concentration} \times \left[\frac{\text{Contact Rate} \times \text{Exposure Frequency}}{\text{Body Weight}} \times \frac{1}{\text{Averaging Time}} \right]$$

$$\text{Cancer Risk} = \text{Slope Factor} \times \text{Intake}$$

$$\text{Hazard} = \frac{\text{Intake}}{\text{Reference Dose}}$$

Putting It All Together – An Example

Cancer Risk and Hazard Results

Exposure to Drinking Water

- **Cancer Risk = 1.1×10^{-4}**
- **Hazard = 3**

Exposure to Soil (Incidental Ingestion)

- **Cancer Risk = 3.7×10^{-5}**
- **Hazard = 0.9**

Trichloroethene is a COC for Soil and Groundwater

Risk Management would determine appropriate actions to address this risk and hazard.

- **Reduce Trichloroethene Concentrations**
- **Reduce Rates of Exposure**

Resources

- EPA's Superfund Risk Assessment Page:
http://www.epa.gov/oswer/riskassessment/risk_superfund.htm
- EPA's Soil Screening Guidance:
http://rais.ornl.gov/calc_start.shtml
- EPA's Regional Screening Tables:
http://epa-prgs.ornl.gov/cgi-bin/chemicals/csl_search
- DOE's Risk Assessment Information System:
<http://rais.ornl.gov/>